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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,607	02/11/2002	Rozlyn A. Krajcik	4555-43U1	5919

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AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/03/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,607

Applicant(s)

KRAJCIK ET AL.

Examiner

Jennifer Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Upon further consideration of the specification and along with Applicants arguments, restriction requirement is reformulated as follows:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 13-19, drawn to a method of treating a disorder of the pilosebaceous apparatus of a mammal, comprising administering an insulin sensitivity increasing substance (i.e. biguanide), classified in class 514, subclass 635.
- II. Claims 1-4, 7-11, 13-19, drawn to a method of treating a disorder of the pilosebaceous apparatus of a mammal, comprising administering an insulin sensitivity increasing substance (i.e. thiazolidinedione), classified in class 514, subclass 439.
- III. Claims 1-4, 7-8, 12-19, drawn to a method of treating a disorder of the pilosebaceous apparatus of a mammal, comprising administering an insulin sensitivity increasing substance (i.e. D-chiro-inositol), classified in class 514, subclass 738.

Art Unit: 1617

- IV. Claims 20-22, 26-30, drawn to a composition for treating a disorder of the pilosebaceous apparatus of a mammal, said composition comprising an ISIS (i.e. thiazolidinedione), classified in class 514, subclass 439.
- V. Claims 20, 23,24, 26-30, drawn to a composition for treating a disorder of the pilosebaceous apparatus of a mammal, said composition comprising an ISIS (i.e.biguanide), classified in class 514, subclass 635.
- VI. Claims 20, 25-30, drawn to a composition for treating a disorder of the pilosebaceous apparatus of a mammal, said composition comprising an ISIS (i.e.D-chiro-inositol), classified in class 514, subclass 738.

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups I-III and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product since the product has been use to treat diabetes mellitus.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and acquired a separate status in the art as shown by their different classification, and the required non-patent

Art Unit: 1617

literature search is not co-extensive. Therefore, restriction for examination purposes as indicated is proper.

Inventions Group I and Groups II-III are independent and distinct each from the other due to separate classification. Therefore, the searches and variation in the use of the claimed active agents renders the claims separate and distinct inventions. The searches as stated above are not co-extensive, particularly in the required literature search. Therefore, restriction for examination purposes is proper.

Inventions Group IV and Groups V-VI are independent and distinct each from the other due to separate classification. Therefore, the searches and variation in the composition of the claimed active agents renders the claims separate and distinct inventions. The searches as stated above are not co-extensive, particularly in the required literature search. Therefore, restriction for examination purposes is proper.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

Art Unit: 1617

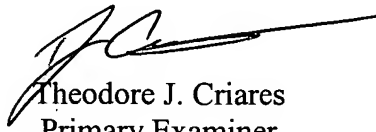
currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

No telephone communication was made on this restriction requirement because the restriction is complex. (MPEP 812.01).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

Application/Control Number: 10/073,607

Page 6

Art Unit: 1617

jmk

May 30, 2003